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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/446,634 | 12/23/1999 | HIROSHI HAGIYA | Q57282 | 2661 |

7590 07/01/2002

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2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

[REDACTED] EXAMINER

HUNT, JENNIFER ELIZABETH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|-----------------|--|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/446,634 | HAGIYA ET AL. | |
| Period for Reply | Examiner | Art Unit | |
| | Jennifer E Hunt | 1642 | |
| <i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. | | | |
| <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | |
| Status | | | |
| 1) <input type="checkbox"/> Responsive to communication(s) filed on _____. | | | |
| 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. | | | |
| 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | |
| Disposition of Claims | | | |
| 4) <input checked="" type="checkbox"/> Claim(s) <u>1-23</u> is/are pending in the application. | | | |
| 4a) Of the above claim(s) _____ is/are withdrawn from consideration. | | | |
| 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. | | | |
| 6) <input type="checkbox"/> Claim(s) _____ is/are rejected. | | | |
| 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. | | | |
| 8) <input checked="" type="checkbox"/> Claim(s) <u>1-23</u> are subject to restriction and/or election requirement. | | | |
| Application Papers | | | |
| 9) <input type="checkbox"/> The specification is objected to by the Examiner. | | | |
| 10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | |
| 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. | | | |
| 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | |
| 13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | |
| 14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. | | | |
| 15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | |
| Attachment(s) | | | |
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . | |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) | |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | | 6) <input type="checkbox"/> Other: _____ . | |

Election/Restrictions

Upon further consideration, in view of a typographical error in the previous restriction requirement which omitted a claim, the previous restriction requirement is withdrawn in light of the following new restriction requirement.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 20, drawn to a plasmid DNA and corresponding therapeutic agent.

Group II, claim(s) 5-19 and 21, drawn to a transformant and corresponding therapeutic agent.

Group III, claim(s) 22-23, drawn to a method for screening an agonist or antagonist.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) a product and process specially adapted for the manufacture of said product; or
- (2) a product and a process of use of said product; or
- (3) a product, a process specially adapted for the manufacture of said product, and a process of use of said product; or

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- (4) a process and an apparatus or means specifically designed for carrying out the process; or
- (5) a product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the process.

In the instant case, Group I contains a product (a plasmid DNA). The products and methods of Groups II-III are distinct from the methods of Group I for the reasons set forth below:

The transformant product of Group II is distinct from the plasmid of Group I because it has a distinct chemical structure, different components, and different physiological and pharmaceutical function.

The method of Group III is a distinct method of using the product of Group II. The method of Group II is different from the products of Group I and II, particularly in that it requires separate components and method steps.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected, applicant must further elect a Fas antigen species:

- A) human
- B) mouse

These are distinct antigens having different chemical structures and physiological properties.

If Group II is elected, applicant must elect a species of nuclear receptor from the group consisting of :

- C) steroid
- D) PPAR α
- E) PPAR δ
- F) PPAR γ
- G) Retanoid X
- H) Retanoic Acid
- I) Vitamin D3
- J) Thyroid Hormone

These are distinct receptors, having different structures, physiological properties and functions.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or

otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons set forth above.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
June 30, 2002

Sheela J. Huff
SHEELA HUFF
PRIMARY EXAMINER